UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ANIKA HUNTE, *as administratrix of the estate of Aries Peterson*, *et al.*,
Plaintiffs,

v.

ABBOTT LABORATORIES, INC.,
Defendant.

No. 3:20-cv-1626 (SRU)

CERTIFICATION ORDER

This case is about the death of a baby—Aries Peterson—who was born prematurely and then spent his entire three-month life in the Neonatal Intensive Care Unit ("NICU") at Yale New Haven Hospital ("YNHH"). Anika Hunte—Aries' mother and the administratrix of his estate—sues Abbott Laboratories, Inc. ("Abbott"), which manufactures the three premature infant formulas that medical professionals fed Aries in this case. Hunte alleges that those formulas, which contain cow's milk, caused Aries to develop necrotizing enterocolitis ("NEC")—an intestinal disease that affects primarily premature infants—and to die. Specifically, Hunte alleges that Abbott violated the Connecticut Product Liability Act (the "CPLA") on several different theories: (1) failure to warn; (2) strict liability for design defect; (3) negligence, (4) negligent misrepresentation; and (5) breach of express warranty. Hunte also alleges that Abbott is liable for intentional misrepresentation and for a violation of the Connecticut Unfair Trade Practices Act. Finally, both Hunte and Aries' father assert claims against Abbott for a loss of filial consortium.

Abbott made a motion to dismiss Hunte's complaint, which I recently granted in part and denied in part. *See* Ruling, Doc. No. 62. As relevant here, I denied Abbott's motion to dismiss without prejudice insofar as it regarded (1) Hunte's failure to warn claim because that claim

depends on a threshold issue regarding whether the learned intermediary doctrine (the "LID") applies, and (2) Aries' parents' loss of filial consortium claims because it is unsettled under Connecticut law whether such claims are cognizable. In my ruling, I indicated that I would soon enter an order certifying relevant and partially controlling questions of law to the Connecticut Supreme Court.

I. Legal Standard

Under Connecticut law, "[t]he Supreme Court may answer a question of law certified to it by a court of the United States . . . if the answer may be determinative of an issue in pending litigation in the certifying court and if there is no controlling appellate decision, constitutional provision or statute of this state." Conn. Gen. Stat. § 51-199b(d); *see also Munn v. Hotchkiss School*, 795 F.3d 324, 334 (2d Cir. 2015). When deciding whether to certify a question to the Connecticut Supreme Court, a court should consider, among other factors: "(1) the absence of authoritative state court decisions; (2) the importance of the issue to the state; and (3) the capacity of certification to resolve the litigation." *Bifolck v. Philip Morris, Inc.*, 2014 WL 585325, at *2 (D. Conn. Feb. 14, 2014) (quoting *O'Mara v. Town of Wappinger*, 485 F.3d 693, 698 (2d Cir. 2007)).

"Certification is especially important in categories of cases where, unless there is certification, the state courts are substantially deprived of the opportunity to define state law." *Munn*, 795 F.3d at 334 (quoting *Gutierrez v. Smith*, 702 F.3d 103, 116 (2d Cir. 2012)). "[S]tate courts should be accorded the first opportunity to decide significant issues of state law through the certification process," and, "especially where the issues implicate the weighing of policy concerns, principles of comity and federalism strongly support certification." *Id.* (quoting *Parrot v. Guardian Life Ins. Co. of Am.*, 338 F.3d 140, 144 (2d Cir. 2003)) (cleaned up). When

"claims implicate important values in the evolution of a state's tort law," certification may be especially appropriate. *Fraser v. United States*, 30 F.3d 18, 20 (2d Cir. 1994).

II. Background[1]

On January 30, 2018, Aries was born at YNHH. Aries weighed 620 grams and had been born at 27 weeks gestation (just over six months). Aries spent his entire life in the NICU at YNHH. Aries died on April 18, 2018. The food that Aries ate during his life is the subject of this lawsuit.

Aries was fed both Hunte's breastmilk[2] and three of Abbott's products: Similac NeoSure ("NeoSure"), Similac Human Milk Fortifier ("Similac HMF"), and Similac Special Care. All three formulas are "exempt" infant formulas, which means that they are intended to feed premature infants. Am. Compl., Doc. No. 44, at ¶ 55.[3] All three formulas contain cow's milk, which Hunte alleges causes NEC. Hunte alleges that Abbott's three "cow's milk-based formula products did cause [] Aries to develop NEC, which triggered severe intestinal disease and death." *Id.* at ¶ 101. Hunte notes that exempt infant formulas need not contain cow's milk: At least one other exempt infant formula (made by Prolacta Bioscience) contains human donor milk. *Id.* at ¶ 104.

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[1] In my ruling on Abbott's motion to dismiss, I gave the parties 30 days to stipulate to a statement of facts. *See* Ruling, Doc. No. 62, at 16–17; Conn. Gen. Stat. § 51-199b(g). I indicated that "[i]f the parties cannot agree, they should merely report by written notice that they cannot agree," in which case "I will identify the relevant facts." Ruling, Doc. No. 62, at 16–17. I put the parties on notice that I "anticipate[d] that my determination of the relevant facts will be identical (or substantially identical) to the 'Factual Background' section of this ruling." *Id.* The parties could not agree upon a statement of facts. Doc. No. 65. Therefore, I have summarized what I take to be the relevant facts in the following section.

[2] Following Aries' birth, Hunte "successfully pumped her own breast milk, and produced a significant supply sufficient for her baby's nutrition." Am. Compl., Doc. No. 44, at ¶ 69.

[3] *Exempt Infant Formulas Marketed in the United States by Manufacturer and Category*, FOOD AND DRUG ADMIN., https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category (last updated Dec. 3, 2019).

On February 16, 2018, Aries was fed a combination of breastmilk and NeoSure. *Id.* at ¶ 70. Later that evening, Aries had bloody stool. *Id.* at ¶ 71. From February 22 through 26, Aries was fed Similac HMF. *Id.* at ¶ 85. On February 25—and for some indeterminate time thereafter—Aries was fed Similac Special Care. *Id.* at ¶ 91.

Hunte reproduces the warning labels for all three formulas. *Id.* at ¶¶ 81 (NeoSure), 89 (Similac HMF), and 95 (Similac Special Care). None mentions NEC or the possibility that using the product could increase the risk of a baby's developing NEC. Hunte does not allege that she saw—or even tried to see—any of those warning labels. NeoSure and Similac Special Care can be bought at retail stores. *Id.* at ¶¶ 78, 94. Hunte never alleges that she ever attempted to buy either.

Most of Hunte's complaint focuses on topics not directly at issue in this case. For instance, Hunte alleges that a growing corpus of scientific research over the past several decades has established that infant formulas containing cow's milk help cause NEC and death in premature infants. *Id.* at ¶¶ 8–25 (citing scientific studies, governmental reports, and policy statements between 1990 and 2017). In fact, according to Hunte, that harm is avoidable: Infant formulas need not contain cow's milk and, for instance, might instead be "derived from human milk." *Id.* at ¶ 10. Hunte spends many paragraphs recounting Abbott's general marketing practices and claiming that those practices were deceptive in various ways—generally, by equating Abbott's products with breastmilk, claiming that Abbott's products were the first choice of doctors, and subtly inferring that Abbott's products were necessary for premature infants to grow properly. *Id.* at ¶¶ 26–66. Hunte alleges that Abbott knew that advertising was false. *See id.* at ¶ 151 ("Abbott has known that their Similac products are significantly increasing the risk of NEC and/or death in premature infants and are aware that there are alternatives to their cow's

milk-based formulas and fortifiers, such as human milk derived products, that would reduce the risk of NEC and/or death, yet they chose to continue to promote, market, and sell their products, causing thousands of premature infants to succumb to NEC and die.").

"All this marketing and promotion," according to Hunte, "is designed to instill confidence in Abbott's product lines, and indeed to plant a subtle seed in a parent's mind that formula is safe and necessary to the growth of a premature infant." *Id.* at ¶ 75. Hunte alleges that, in general, she "was exposed [to] and persuaded by marketing from Abbott that Similac products were safe and necessary to the growth and nutrition of her premature infant." *Id.* at ¶ 76. Hunte also alleges that she "was enticed into joining *Similac Strong Moms Rewards*," which appears to have been a mailing list for formula coupons. *Id.* at ¶ 166. Hunte alleges that, through her membership in *Similac Strong Moms Rewards*, Abbott "gained access to substantial private information" about Hunte and targeted her with ads, such as a January 18 email,[4] which Hunte received while she was hospitalized. *Id.* at ¶ 167–68. Importantly, Hunte does not allege that she ever saw or read that email—only that she received it. *See id.* at ¶ 168.

Hunte alleges very few facts regarding the three formulas at issue and no facts regarding the connection between the advertising of those three formulas and Hunte. So far as I can tell, Hunte makes no specific allegations regarding Similac HMF or Similac Special Care. With respect to NeoSure, Hunte's allegations are general, vague, and not clearly relevant. For instance, Hunte cites to Similac's website and notes that "Similac promotes *Neosure*" without mentioning NEC. *Id.* at ¶¶ 57–58; 73–74. Hunte also performed "Google search[es]" for "feeding preemies formula," "Is formula healthy for premature infants?" and "Is formula safe for

[4] Hunte does not allege much regarding the contents of that January 18 email. Hunte alleges only that "[t]he email contains various links which are designed to message the quality of Abbott's brands and control the message regarding the nutritional needs of babies." Am. Compl., Doc. No. 44, at ¶ 168.

premature infants?"; Hunte notes that paid advertisements for NeoSure appeared in response to each search. *Id.* at ¶¶ 56, 59–60. Those advertisements do not mention NEC.

The following few paragraphs of Hunte's complaint provide a helpful summary of the connection, in Hunte's view, between Abbott's generalized advertising and Aries' death:

> The pervasive exposure by mothers to media, advertising and promotion equating human milk to breastmilk has the generalized impact of: (a) reducing lactation; (b) causing mothers to believe formula is comparable to breastmilk; and (c) reduc[ing] the capacity for informed consent and informed decision-making. Through long-term exposure to Abbott's advertising, [] Aries['] mother had been conditioned and was caused to believe that Similac products are suitable alternatives to breastmilk and necessary supplements for low birth weight infants.

Id. at ¶ 36.

> Abbott has designed a systematic, powerful and misleading marketing campaign to deceive mothers to believe that: (1) cow milk formula and fortifier is safe; (2) cow-milk products are equal, or even superior, substitutes to breastmilk; and (3) Physicians consider their cow's milk-based products a first choice. Similarly, Abbott has marketed its products for premature infants as necessary for "catch-up growth", and perfectly safe for premature infants, despite knowing of the extreme risks posed by cow's milk-based products relative to the deadly disease of NEC with regard to premature infants and cow products. Anika Hunte was exposed to this deception, and was caused to believe this deception, all [of] which substantially contributed to her baby being fed the defendant's cow milk products.

Id. at ¶ 65.

> Members of the medical community, physicians, and hospitals, as well as the parents, relied upon the representations and advertising of the defendant, which categorically omit that their cow's milk-based products significantly increase the risk of NEC and death in premature infants, which contributed to the product being fed to [] Aries.

Id. at ¶ 66.

II. Discussion

A. Learned Intermediary Doctrine

1. The Law

In Connecticut, "a manufacturer's duty to warn of dangers associated with its products pertains only to known dangers and runs to the ultimate consumer of those products." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 375 (2001). The LID—a feature of state common law—"is an exception to this general rule." *Id.* First announced in an Eighth Circuit case in 1966, the LID is a "rule of law stating a duty, i.e., that a drug manufacturer has a duty to warn prescribing physicians of the dangers associated with its product, and not the ultimate consumer." *Id.* at 382, 393; *see Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966)). "The existence of a duty is a question of law and only if such a duty is found to exist does the trier of fact then determine whether the defendant violated that duty in the particular situation at hand." *RK Constructors, Inc. v. Fusco Corp.*, 231 Conn. 381, 384 (1994) (quoting *Petriello v. Kalman*, 215 Conn. 377, 382–83 (1990)) (cleaned up).

The LID "provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly." *Vitanza*, 257 Conn. at 376 (cleaned up). The LID "is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment." *Id.* (quoting *Vitanza v. Upjohn Co.*, 48 F. Supp. 2d 124, 127 (D. Conn. 1999)) (cleaned up).

Although "[f]ederal courts sitting in diversity have applied the learned intermediary doctrine as a matter of Connecticut law" since the late 1960s, it was not until 2001 that the Connecticut Supreme Court confirmed that Connecticut's "strict liability jurisprudence includes the learned intermediary doctrine." *Id.* at 378–79. In *Vitanza*, the Connecticut Supreme Court held that the LID applied to—and barred—a widow's failure to warn claim against a drug

manufacturing company after her husband "died as a result of ingesting a sample of a prescription drug given to her by her physician." *Id.* at 367. In confirming the LID's application in that case, the *Vitanza* Court noted that the LID "applies particularly to the medical field, and generally involves unavoidably unsafe products . . . which by law can go from the manufacturer to the consumer only by way of a prescribing physician." *Id.* at 390. The *Vitanza* Court explained that important indicators for determining whether the LID should apply include (1) a "highly personal doctor-patient relationship" and (2) "the fact that the product can be obtained legally only from a physician." *Id.* at 391.[5]

Courts have extended the LID's application to failure to warn claims regarding products other than prescription drugs. For instance, in 2006 the Connecticut Supreme Court extended the LID to a case involving a prescription medical device (pacemaker). *See Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 316–17 (2006). In doing so, the *Hurley* Court noted that "we can see no principled reason to distinguish between a prescription implantable medical device like a pacemaker and a prescription drug." *Id.* at 317. Other courts—in Connecticut and around the country—have applied the LID in cases regarding products other than prescription drugs, such as MRI contrast agents,[6] x-ray machines,[7] and contact lenses.[8]

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[5] In applying the LID before *Vitanza*, several federal courts construing Connecticut law focused on the same factors. *See, e.g.*, *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 18 (D. Conn. 1989) (explaining that the LID depends on the idea that a patient's treating physician "make[s] a careful, balanced assessment of the risks and benefits to her patient"); *Goodson v. Searle Labs., Inc.*, 471 F. Supp. 546, 548–49 (D. Conn. 1978) ("[T]he drug can be used only under the professional supervision of a doctor licensed by law to administer the drug."); *Hall v. Ashland Oil Co.*, 625 F. Supp. 1515, 1518–20 (D. Conn. 1986) (focusing also on the fact that "a physician has a fiduciary relationship with a patient" and so the doctor's "primary purpose in selecting a drug is to promote the well-being of the ultimate user").

[6] *See Zelle v. Bayer Healthcare, LLC*, 2012 WL 753796, at *5 (Conn. Super. Ct. Feb. 16, 2012).

[7] *See Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985).

[8] *See Perotti v. Johnson & Johnson Vision Prods., Inc.*, 2004 WL 3016092, at *4–5 (Ohio Ct. App. Dec. 30, 2004).

Courts seem to decide whether the LID applies in a particular case by considering the type of product at issue. *See, e.g.*, *Vitanza*, 257 Conn. at 367 ("The learned intermediary doctrine provides, in general terms, that adequate warnings to a prescribing physician obviate the need for a manufacturer *of a prescription drug* to warn ultimate consumers.") (emphasis added); *Hurley*, 278 Conn. at 317 (extending the LID from "the context of prescription drugs" to "prescription medical device cases"). In general, courts have applied the LID in cases involving *prescription* products and have not applied the LID in cases involving *non-prescription* products that are available over the counter.[9] In her motion to certify, Hunte relies heavily on that prescription/non-prescription distinction. *See* Hunte's Mem. of Law in Supp. Mot. to Certify, Doc. No. 47-1, at 7–10. Relatedly, I am aware of no court that has held that the medical use of a non-prescription product can bring that product within the LID's scope.

Connecticut courts have not explicitly identified or analyzed that prescription/non-prescription distinction. Plainly, using that distinction to determine whether the LID applies in a particular case has certain benefits. First, it is an easily administrable, bright-line rule. Second, it easily captures most cases in which the LID will apply: Doctors are necessary intermediaries for prescription products whereas a consumer can him- or herself purchase a non-prescription product. That is obviously an important consideration in determining whether the LID should

[9] *See, e.g.*, *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014) ("Defendants had no duty to inform physicians . . . because Children's Motrin is an over-the-counter drug."); *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1276 (5th Cir. 1974) ("Pharmaceutical companies . . . must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter" but "in selling prescription drugs are required to warn only the prescribing physician"); *Prager v. Allergan, Inc.*, 1990 WL 70875, at *4 (N.D. Ill. May 2, 1990) (refusing to extend LID to "non-prescription contact lens cleaner"—even though plaintiff's "physician recommended" the product—because it was "sold with package inserts designed to inform the average consumer," "could have [been] obtained and used without the recommendation," and the plaintiff "was free to use another lens cleaner"); *Mitchell v. VLI Corp.*, 786 F. Supp. 966, 970 (M.D. Fla. 1992) (declining to apply the LID because the plaintiff "could have obtained the sponge over-the-counter," and so "it would be illogical to treat her differently based on the mere fortuity that she obtained a sample of the sponge from her physician"); *Torsiello v. Whitehall Labs., Div. of Home Prods. Corp.*, 165 N.J. Super. 311, 323–25 (App. Div. 1979) (citing cases differentiating between prescription and non-prescription).

apply, and the courts that have emphasized the prescription/non-prescription distinction rely mostly on that salient fact. *See, e.g.*, *Torsiello v. Whitehall Labs., Div. of Home Prods. Corp*, 165 N.J. Super. 311, 322 (App. Div. 1979) ("[T]he duty of the manufacturer explicitly to warn consumers of the specific risks of over-the-counter drug use derives from the basic marketing predicate of the over-the-counter drug industry, namely, that nonprescription drugs are purchased by consumers for the purpose of self-medication typically without any intended or actual intervention by a physician."); *Prager v. Allergan, Inc.*, 1990 WL 70875, at *4 (N.D. Ill. May 2, 1990); *Mitchell v. VLI Corp.*, 786 F. Supp. 966, 970 (M.D. Fla. 1992).

However, no court invoking the strict prescription/non-prescription distinction presided over a case involving exempt infant formula—or anything similar in kind. In my view, the strict prescription/non-prescription distinction does not apply neatly in this case because exempt infant formulas are a hybrid between prescription and non-prescription products. For instance, some exempt infant formulas appear to be available for general retail purchase, but others do not. *Compare* 21 C.F.R. § 107.50(b) ("Infant formulas generally available at the retail level") *with id.* § 107.50(c) ("Infant formulas not generally available at the retail level"). Indeed, Hunte's own allegations in this case confirm that fact: Hunte alleges that NeoSure and Similac Special Care can be bought at retail stores. *Id.* at ¶¶ 78, 94. But Hunte does not allege that Similac HMF can be bought at retail stores. Further, Hunte never alleges that she ever attempted to buy either NeoSure or Similac Special Care: Those products were administered to Aries exclusively in the highly medical context of the NICU at YNHH.

Because of the highly medical atmosphere in which the products at issue were administered—and because some of the products appear available for purchase while others do not—the prescription/non-prescription distinction on which other courts have relied is relatively

unhelpful in this case. Thus, whether the LID applies to the products at issue in this case—either in general or on the facts of this case—is unclear.

If the Connecticut Supreme Court determines that the LID does apply in this case, the next consideration is whether this case falls within an exception to the LID. Some courts (in foreign jurisdictions) have recognized certain exceptions to the LID. "The central theme" among those cases "is that the physician-patient relationship is not the same as in typical treatment scenarios." Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, The Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 1009 (2001); *see also Vitanza*, 257 Conn. at 393 (noting that those exceptions, in general, "involve situations where there is a lack of communication between patients and their physicians or where patients essentially control the selection of the product"). Examples of those situations include: (1) mass immunization clinics, *see Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130–31 (9th Cir. 1968); (2) when a physician takes a passive, secondary role in the patient's treatment, *see Hill v. Searle Labs.*, 884 F.2d 1064, 1070–71 (8th Cir. 1989) (declining to apply LID regarding patient's intrauterine device because patient makes primary decision to seek birth control prescription and, if so, method of birth control); *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 136–37 (Mass. 1985) (same for oral contraceptives); (3) overpromoted drugs, *see Proctor v. Davis*, 291 Ill. App. 3d 265, 279–84 (1997); and (4) drugs withdrawn from the market, *see Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 565 (D. Mich. 1993). The *Vitanza* Court acknowledged that those exceptions exist in other jurisdictions, but it did not decide whether Connecticut law recognizes any of them. *Vitanza*, 257 Conn. at 393–94. So far as I am aware, no Connecticut court since *Vitanza* has addressed whether Connecticut law

recognizes any exceptions to the LID. *See Swoverland v. GlaxoSmithKline*, 2011 WL 6001864, at *2 (D. Conn. Oct. 5, 2011) (noting the same as of 2011).

2. Discussion

In my view, it is unclear whether the LID applies to Hunte's failure to warn claim. Thus, it is unclear whether Abbott owed a duty to warn (1) medical professionals or (2) Aries' parents. Without knowing to whom the duty was owed, I cannot evaluate the adequacy of Abbott's warnings, and so I cannot decide whether to grant or deny Abbott's motion to dismiss on that ground. Although the resolution of that issue will not be dispositive of this case, it may be dispositive of Hunte's failure to warn claim, and other considerations weigh strongly in support of certification.

So far as I can tell, no court has yet decided whether the LID applies to exempt infant formulas, which are intended for use on premature infants. In my view, that issue presents a close question. Answering that question will involve evaluating the reasons undergirding application of the LID and balancing important policy considerations. The Connecticut Supreme Court deserves the chance to weigh in on that important issue of state law, which is likely to recur in this precise factual setting[10] and in other analogous ones.

It is difficult for me to predict how the Connecticut Supreme Court will resolve the issue. Neither the Connecticut Supreme Court nor any Connecticut lower court has addressed it. *See Maska U.S., Inc. v. Kansa Gen. Ins. Co.*, 198 F.3d 74, 78 (2d Cir. 1999) (explaining that regarding issues of unsettled state law, a federal court "must carefully predict how the state's highest court would resolve the uncertainty or ambiguity," and, "[i]n making this prediction," a

[10] In fact, this is the second case before me in which the issue has arisen. *See Ferry v. Mead Johnson, et al.*, No. 3:20-cv-99 (SRU). In addition, similar cases have been filed in other jurisdictions. *See, e.g.*, Hunte's Notice of New Authority, Doc. No. 61 (Florida).

federal court should "give the fullest weight to pronouncements of the state's highest court . . . while giving proper regard to relevant rulings of the state's lower courts") (cleaned up). Indeed, so far as I am aware, no court anywhere has addressed whether the LID applies to a nutritional product, either categorically or on the particular facts of that case.

On the one hand, the Connecticut Supreme Court may be unlikely to extend the LID to cases involving exempt infant formulas. Although courts in Connecticut and beyond have applied the LID to cases involving products other than prescription drugs, no court (so far as I am aware) has applied the LID to a non-prescription product of any sort. Abbott's exempt infant formulas are not prescription products. In addition, it appears that no court anywhere has applied the LID to a case involving a nutritional product. Abbott's exempt infant formulas are food.

On the other hand, there may be compelling reasons to extend the LID to cover exempt infant formulas. Exempt infant formulas are hybrid products—somewhere in between prescription products and over-the-counter products. As described above, some exempt infant formulas are apparently available at a general retail level, but other exempt infant formulas are not. Indeed, in this very case, Hunte alleges that two of the three formulas at issue were available at retail. Further, if the context in which a product is used factors into the determination whether the LID applies in a particular instance, the case for applying the LID here becomes especially strong. Abbott's products were used exclusively in the context of a highly regulated medical environment. Aries spent his entire life in the NICU at YNHH under the care of medical professionals. It is probable that many failure to warn cases involving exempt infant formulas will regard an infant whose life was spent in the NICU.

Exempt infant formulas, then, share many important qualities with prescription drugs, particularly on the facts of this case. In that way, this case resembles prototypical cases in which

courts have determined that the LID applies. Just as a doctor examines a patient and then prescribes the patient drugs, the YNHH doctors cared for Aries and fed him Abbott's products to help nurse him to health.

As described above, some courts in foreign jurisdictions have explicitly decided not to apply the LID in cases regarding non-prescription products. I agree that, in the usual case, the LID will not apply to products that are available over the counter. For instance, if this case regarded a parent's decision to give Children's Motrin to a 3-year-old, *see Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014), or an adult's choice to take Anacin (aspirin and caffeine) every day for 14 months to treat his arthritis, *see Torsiello*, 165 N.J. Super. at 324–26, I would agree that the LID should not apply, and that the Defendants' duty to warn would run to the consumer.

However, exempt infant formulas seem unique in that they are a hybrid between prescription and over-the-counter products. This is not a case in which a consumer walks into a pharmacy and chooses a product from among several similar products stacked next to each other on a shelf. Exempt infant formulas are targeted at vulnerable infants who (most likely) will begin their lives in the NICU under medical professionals' full-time care. In the normal course, parents of a premature infant confined in a NICU will rely on medical personnel—or work in consultation with them—in determining how to nourish their baby.

If the LID does apply to exempt infant formulas—or at least applies in this case—the question arises whether an exception to the LID applies. So far as I am aware, since *Vitanza*, no lower Connecticut courts have shed light on the question whether any exceptions to the LID exist under Connecticut law. *See Swoverland*, 2011 WL 6001864, at *2 (noting the same in 2011). Exceptions to the LID all "involve situations where there is a lack of communication between

patients and their physicians or where patients essentially control the selection of the product." *Vitanza*, 257 Conn. at 393. In this case, the physician-patient relationship was typical. In fact, the YNHH doctors' monitoring Aries were almost surely more intense and all-encompassing than a doctor's monitoring a patient for whom he or she prescribes a drug. Thus, it seems likely that no exception would apply (even if one existed).

However, some courts have adopted an exception to the LID regarding products that are marketed directly to consumers (the "DTC exception"). Although courts in some jurisdictions have adopted the exception, many have not.[11] In fact, the weight of authority seems to suggest that those courts that have adopted the DTC exception—particularly the New Jersey Supreme Court in *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1 (1999)—are outliers. *See, e.g.*, *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376–77 (S.D. Fla. 2007) (anticipating that the Florida Supreme Court would not adopt the DTC exception because, in the then-eight years since *Perez*, "no other state has followed suit"). Other courts have noted that they will only cautiously recognize new exceptions to the LID. *See Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 567 (E.D. Pa. 2020).

If the DTC exception exists under Connecticut law, it is unclear whether it would apply in this case. Some considerations seem to support its application. Two of the three exempt infant formulas at issue are apparently available at retail. And Hunte spends many paragraphs in her complaint recounting Abbott's long history of marketing its infant formulas. In general, the

[11] *Compare Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 970 (S.D. Tex. 2012) (declining to apply LID to Humira, a prescription drug, because Abbott "directly marketed to Murthy by creating and disseminating a promotional video" and "Abbott compensated Murthy's physician") *and Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 19 (1999) (declining to apply LID to implantable contraceptive device in part because "[c]onsumer-directed advertising of pharmaceuticals ... belies each of the premises on which the learned intermediary doctrine rests.") *with Murthy*, 847 F. Supp. 2d at 969–70 (citing several cases that have declined to recognize DTC exception, including *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007); *Cowley v. Abbott Labs., Inc.*, 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wisc. 2007); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006), *judgment vacated on other grounds by Colacicco v. Apotex, Inc.*, 556 U.S. 1101 (2009)).

more Abbott marketed its exempt infant formulas to the general public, the stronger the case for applying the DTC exception.

On the other hand, the DTC exception may not apply to exempt infant formulas, particularly on the facts of this case. Most importantly, the use of the exempt infant formulas in this case was a medical decision: There is no suggestion that Aries' parents advocated for their use. Similarly, Hunte (at least arguably) does not allege that Abbott's marketing had any effect on her or on Aries' father. Thus, even if the DTC exception to the LID applied—and thus Abbott's duty to warn ran to Aries' parents—it is unclear whether causation would be satisfied. *See Bifolck v. Philip Morris*, 324 Conn. 402, 433–34 (2016) (noting that, in all product liability claims, the plaintiff must prove that "the defect caused the injury for which compensation was sought").

B. Loss of Filial Consortium

As described in my recent ruling on Abbott's motion to dismiss, Aries' parents bring claims for loss of filial consortium. I denied without prejudice Abbott's motion to dismiss because, in my view, "[i]t is an open question whether Connecticut law recognizes a cause of action for loss of filial consortium." Ruling, Doc. No. 62, at 37. As I explained, Connecticut law recognizes causes of action for loss of spousal consortium, *see* Conn. Gen. Stat. § 52-555a, and loss of parental consortium, *see Campos v. Coleman*, 319 Conn. 36, 43 (2015). But, lower courts in Connecticut appear split regarding whether Connecticut law recognizes a claim for loss of filial consortium. *Compare Perez v. Stanford*, 2021 WL 828560, at *1 (Conn. Super. Ct. Jan. 19, 2021) (exists) *and Joshua Isaac Monroe Lynch, PPA, et al. v. State of Connecticut, et al.*, 2021 WL 3487733, at *48–49 (Conn. Super. Ct. June 28, 2021) (same) *with Zamora-George v. Yale New Haven Hospital, Inc.*, 2020 WL 1656201, at *3–4 (Conn. Super. Ct. Feb. 21, 2020)

(does not exist) *and Vincent v. Yale New Haven Health Servs. Corp.*, 2018 WL 7107584, at *2 (Conn. Super. Ct. Dec. 27, 2018) (same) *and Angeles v. State, Dep't of Children and Families*, 2017 WL 5203245, at *7 (Conn. Super. Ct. Oct. 10, 2017) (same).

In my view, certifying this issue is appropriate because whether a cause of action for loss of filial consortium exists will "be determinative of an issue in [this] pending litigation," and "there is no controlling appellate decision, constitutional provision or [Connecticut state] statute" providing the answer. Conn. Gen. Stat. § 51-199b(d); *see also* Hr'g Tr., Doc. No. 57, at 11:22–24 (Abbott's counsel agreeing that issue should be certified); *id.* at 26:17–21 (Hunte's counsel conceding that this is an "unsettled" and "undeveloped area under Connecticut law"). Whether a cause of action for loss of filial consortium exists under Connecticut state law presents a sensitive issue of tort law within the peculiar province of the state, and the answer will involve weighing important policy considerations. *See Munn v. Hotchkiss School*, 795 F.3d 324, 334 (2d Cir. 2015) ("[S]tate courts should be accorded the first opportunity to decide significant issues of state law through the certification process, . . . especially where the issues implicate the weighing of policy concerns . . . .") (quoting *Parrot v. Guardian Life Ins. Co. of Am.*, 338 F.3d 140, 144 (2d Cir. 2003)) (cleaned up); *Fraser v. United States*, 30 F.3d 18, 20 (2d Cir. 1994) (explaining that certification may be especially appropriate when "claims implicate important values in the evolution of a state's tort law"); *cf. Campos*, 319 Conn. at 43–51 (weighing policy considerations in deciding whether to recognize cause of action for loss of parental consortium). The Connecticut Supreme Court deserves the opportunity to address this issue in the first instance.

III. Questions for Certification

Because "the answer[s] may be determinative of an issue in pending litigation" in this court and because "there [exists] no controlling appellate decision, constitutional provision or

statute" of Connecticut, *see* Conn. Gen. Stat. § 51-199b(d), the following questions are certified to the Supreme Court of Connecticut:

(1) In general, does the learned intermediary doctrine apply to failure to warn claims brought under the Connecticut Product Liability Act, Conn. Gen. Stat. § 52-572m, *et seq.*, that involve exempt infant formulas?

(2) Even if not, does the learned intermediary doctrine apply to Abbott's products on the facts of this case, given the medical context in which they were used and how they were administered?

(3) If the learned intermediary doctrine applies either generally or on the facts of this case, does the direct-to-consumer exception to the learned intermediary doctrine (or any other exception) apply?

(4) Does Connecticut law recognize a cause of action for loss of filial consortium?

The Connecticut Supreme Court may, of course, reformulate those questions as it sees fit or include additional questions in any certification order. Additionally, this court will make available to the Connecticut Supreme Court any part of the record in this case that will assist that Court in its review.

IV. Counsel of Record

According to Conn. Gen. Stat. § 51-199b(f)(4), I must include "[t]he names and addresses of counsel of record and unrepresented parties." The counsel of record are as follows.

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So ordered.

Dated at Bridgeport, Connecticut, this 26th day of October 2021.

/s/ STEFAN R. UNDERHILL
Stefan R. Underhill
United States District Judge